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10/765,943	01/29/2004	Yasuyuki Numajiri	00862.023438.	1830

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FITZPATRICK CELLA HARPER & SCINTO  
30 ROCKEFELLER PLAZA  
NEW YORK, NY 10112

EXAMINER
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SHAW, AMANDA MARIE

ART UNIT	PAPER NUMBER
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1634

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07/24/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/765,943	<b>Applicant(s)</b> NUMAJIRI, YASUYUKI	
	<b>Examiner</b> Amanda Shaw	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 28-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 29, 2009 has been entered.

Claims 28-33 are currently pending. Claims 32 and 33 have been amended.

### **Withdrawn Rejections**

2. The rejection made under 35 USC 101 in section 3 of the Office Action of January 29, 2009 is withdrawn in view of amendments to the claims.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**4. Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hogan (US 2002/0110823 Pub 8/2002 Filed 10/2001) in view of Kris (US 6238869 Issued 2001) and Beecham (US Patent 5876926 Issued 1999).**

Hogan teaches a method wherein a sample from a perioperative subject is used to generate a genomic profile for that subject. Hogan teaches that in some embodiments the genomic profile includes a set of markers that provide information that can be used to determine the course of treatment (Para 0126). Hogan further teaches that in some embodiments the genomic profile includes a set of unique genomic identifiers (e.g., a series of polymorphic non coding SNPs) used to determine the identity of the subject (Para 0134). Additionally Hogan teaches that in preferred embodiments the genomic profiles are generated by hybridizing a genomic DNA sample to a DNA microarray and detecting hybridization (Para 0167-0176 and Para 210). Genomic DNA samples are expected to include genes suitable for personal identification and disease related genes. Thus Hogan teaches a method that comprises hybridizing a solution of DNA including genes suitable for personal identification and disease related genes to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject. Hogan also teaches that after the sequence information has been generated the information can be stored (e.g., as digital information on a portable chip) (para 0186). Thus Hogan teaches a method further comprising recording the test

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information onto a medical information card (clm 29), a method further comprising storing the test information into a storing means (clm 31), a method further comprising writing the test information into a memory unit (clm 32), a method further comprising outputting the test information so that the test information is stored on a computer readable storage medium (clm 33). Each of these limitations are essentially saying the same thing in a different way. The teachings of Hogan (para 0186) meet each of these limitations.

Hogan does not teach a method wherein the microarray has two separated areas one of which is an area where probes of the first DNA probe group are arranged, and another of which is an area where the probes of the second group are arranged.

However Kris teaches a microarray comprising a plurality of at least two discrete regions (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hogan by using a microarray that has two separated arrays as suggested by Kris. One of skill in the art would have been motivated to use the array of Kris when practicing the method of Hogan because the array of Kris allows one to analyze the presence of one or more targets (i.e. genes for personal identification and disease related genes) at the same time. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing a microarray with two separate areas wherein the first area contains probes for personal identification and the second area contains probes for checking on a health condition of the subject.

Therefore, modifying the method of Hogan by using a microarray that has two separated arrays was prima facie obvious to one of ordinary skill in the art at the time of the invention.

Additionally Hogan does not teach a method comprising acquiring information recorded on a medical card owned by the subject and comparing the identification information from the microarray to the identification information on the medical card. Further Hogan does not teach a step of displaying a warning and inhibiting the test information from being written into the memory unit if the comparison result of the comparison step indicates that the first identification information and the second identification information do not match (clm 32) or an inhibiting step of displaying a warning and inhibiting execution of the second reading step, the generation step, and the output step if the comparison result of the comparison step indicates that first identification information and the second identification information do not match (clm 33)

However Beecham teaches a method wherein biometric data submitted by a user is compared to stored biometric data (column 18, lines 8-20). In the instant case the biometric data submitted by the user is being interpreted as the identification information from the microarray and the stored biometric data is being interpreted as the identification information on the medical card (i.e., storage device). Beecham teaches that when the biometric data submitted by the user matches the stored biometric data then the medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card and releasing medical data when there is

a match. Beecham further teaches that when the biometric data (identification information from the microarray) does not match stored biometric data (information on the medical ID card) a request for new or revised biometric data is sent and no test information is released until there is a match (col 18, lines 14-20). As such Beecham teaches a step of displaying a warning and inhibiting the test information from being released if the comparison result of the comparison step indicates that the first identification information and the second identification information do not match.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hogan by comparing the identification information on the microarray to the identification information on the medical card before recording the patients test results on the medical card as suggested by Beecham. One of skill in the art would have been motivated to make the comparison in order to prevent someone from obtaining someone else's private medical information. Further it would have been obvious to inhibit the execution of the second reading step, the generation step, and the output step if the comparison result of the comparison step indicates that first identification information and the second identification information do not match to also prevent someone from obtaining someone else's private medical information.

**5. Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barrett (US 2005/0064436 Filed 3/2005) in view of Kris (US 6238869 Issued 2001) and Beecham (US Patent 5876926 Issued 1999).**

Barrett teaches a method wherein a SNP profile is determined for a nucleic acid sample, where the determined SNP profiled is then employed to identify the source of the sample, e.g., the subject or patient from which the sample was obtained. Barrett further teaches that the sample can also be used to screen for a condition, e.g., a disease. In some embodiments the sample is screened for a SNP profile and a disease simultaneously using an array of probes wherein the array includes both SNP probe features and disease probe features (para 0063). Barrett teaches that the sample may be genomic DNA which is expected to include genes suitable for personal identification and disease related genes. Thus Barrett teaches a method that comprises hybridizing a DNA sample including genes suitable for personal identification and disease related genes to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject. Barrett further teaches that after the sequence information has been generated the information can be stored (e.g., as digital information in a database) (para 0053-0055). Thus Barrett teaches a method further comprising recording the test information onto a medical information card (clm 29), a method further comprising storing the test information into a storing means (clm 31), a method further comprising writing the test information into a

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memory unit (clm 32), a method further comprising outputting the test information so that the test information is stored on a computer readable storage medium (clm 33). Each of these limitations is essentially saying the same thing in a different way. The teachings of Barrett (paras 0053-0055) meet each of these limitations.

Barrett does not teach a method wherein the microarray has two separated areas, one of which is an area where probes of the first DNA probe group are arranged, and another of which is an area where the probes of the second group are arranged.

However Kris teaches a microarray comprising a plurality of at least two discrete regions (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Barrett by using a microarray that has two separated arrays as suggested by Kris. One of skill in the art would have been motivated to use the array of Kris when practicing the method of Hogan because the array of Kris allows one to analyze the presence or one or more targets (i.e. genes for personal identification and disease related genes) at the same time. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing a microarray with two separate areas wherein the first area contains probes for personal identification and the second area contains probes for checking on a health condition of the subject. Therefore, modifying the method of Barrett by using a microarray that has two separated arrays was prima facie obvious to one of ordinary skill in the art at the time of the invention.

Additionally Barrett does not teach a method comprising acquiring information recorded on a medical card owned by the subject and comparing the identification information from the microarray to the identification information on the medical card. Further Barrett does not teach a step of displaying a warning and inhibiting the test information from being written into the memory unit if the comparison result of the comparison step indicates that the first identification information and the second identification information do not match (clm 32) or an inhibiting step of displaying a warning and inhibiting execution of the second reading step, the generation step, and the output step if the comparison result of the comparison step indicates that first identification information and the second identification information do not match (clm 33)

However Beecham teaches a method wherein biometric data submitted by a user is compared to stored biometric data (column 18, lines 8-20). In the instant case the biometric data submitted by the user is being interpreted as the identification information from the microarray and the stored biometric data is being interpreted as the identification information on the medical card. Beecham teaches that when the biometric data submitted by the user matches the stored biometric data then the medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card and releasing medical data when there is a match. Beecham further teaches that when the biometric data (identification information from the microarray) does not match stored biometric data (information on the medical ID card) a request for new or revised biometric data is sent and no test

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information is released until there is a match (col 18, lines 14-20). As such Beecham teaches a step of displaying a warning and inhibiting the test information from being released if the comparison result of the comparison step indicates that the first identification information and the second identification information do not match

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Barrett by comparing the identification information on the microarray to the identification information on the medical card before recording the patients test results on the medical card as suggested by Beecham. One of skill in the art would have been motivated to make the comparison in order to prevent someone from obtaining someone else's private medical information. Further it would have been obvious to inhibit the execution of the second reading step, the generation step, and the output step if the comparison result of the comparison step indicates that first identification information and the second identification information do not match to also prevent someone from obtaining someone else's privated medical information.

**6. Claims 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashmi (US 2004/0048259 Filed 9/2002) in view of Kris (US 6238869 Issued 2001) and Beecham (US Patent 5876926 Issued 1999).**

Hashmi teaches a method for genetic testing of an organism and for correlating the results of the genetic testing with a unique marker (i.e. SNP profile) that unambiguously identifies the organism (Abstract). Hashmi teaches that patients sample is contacted with a first set of probes that is used in an assay designed for genetic testing and the second set of probes is used in the determination of a molecular fingerprint (para 0089). Hashmi further teaches that the patients sample may be genomic DNA which is expected to include genes suitable for personal identification and disease related genes (para 0061). Thus Hashmi teaches a method that comprises hybridizing a DNA sample including genes suitable for personal identification and disease related genes to a DNA microarray with probes capable of being used to identify a subject and probes capable of being used to check on the health of a subject. By reading and analyzing the hybridization pattern on the array it is possible to determine the identity of the subject and obtain health related test information for the subject. Hashmi further teaches that after the sequence information has been generated the information can be stored in a database (para 0131). Thus Hashmi teaches a method further comprising recording the test information onto a medical information card (clm 29), a method further comprising storing the test information into a storing means (clm 31), a method further comprising writing the test information into a memory unit (clm 32), a method further comprising outputting the test information so that the test information is stored on a computer readable storage medium (clm 33). Each of these limitations is essentially saying the same thing in a different way. The teachings of Hashmi (para 0131) meet each of these limitations.

Hashmi does not teach a method wherein the microarray has two separated areas, one of which is an area where probes of the first DNA probe group are arranged, and another of which is an area where the probes of the second group are arranged.

However Kris teaches a microarray comprising a plurality of at least two discrete regions (abstract).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hashmi by using a microarray that has two separated arrays as suggested by Kris. One of skill in the art would have been motivated to use the array of Kris when practicing the method of Hashmi because the array of Kris allows one to analyze the presence or one or more targets (i.e. genes for personal identification and disease related genes) at the same time. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing a microarray with two separate areas wherein the first area contains probes for personal identification and the second area contains probes for checking on a health condition of the subject. Therefore, modifying the method of Hashmi by using a microarray that has two separated arrays was prima facie obvious to one of ordinary skill in the art at the time of the invention.

Additionally Hashmi does not teach a method comprising acquiring information recorded on a medical card owned by the subject and comparing the identification information from the microarray to the identification information on the medical card. Further Hashmi does not teach a step of displaying a warning and inhibiting the test

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information from being written into the memory unit if the comparison result of the comparison step indicates that the first identification information and the second identification information do not match (clm 32) or an inhibiting step of displaying a warning and inhibiting execution of the second reading step, the generation step, and the output step if the comparison result of the comparison step indicates that first identification information and the second identification information do not match (clm 33)

However Beecham teaches a method wherein biometric data submitted by a user is compared to stored biometric data (column 18, lines 8-20). In the instant case the biometric data submitted by the user is being interpreted as the identification information from the microarray and the stored biometric data is being interpreted as the identification information on the medical card. Beecham teaches that when the biometric data submitted by the user matches the stored biometric data then the medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card and releasing medical data (the results of the second DNA probe group) when there is a match. Beecham further teaches that when the biometric data (identification information from the microarray) does not match stored biometric data (information on the medical ID card) a request for new or revised biometric data is sent and no test information is released until there is a match (col 18, lines 14-20). As such Beecham teaches a step of displaying a warning (i.e., the request for new or revised biometric data) and inhibiting the test information from being released

if the comparison result of the comparison step indicates that the first identification information and the second identification information do not match

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Hashmi by comparing the identification information on the microarray to the identification information on the medical card before recording the patients test results on the medical card as suggested by Beecham. One of skill in the art would have been motivated to make the comparison in order to prevent someone from obtaining someone else's private medical information. Further it would have been obvious to inhibit the execution of the second reading step, the generation step, and the output step if the comparison result of the comparison step indicates that first identification information and the second identification information do not match to also prevent someone from obtaining someone else's private medical information.

### ***Response To Arguments***

8. In the response filed May 29, 2009 the applicants traversed the rejections made over Hogan, Barrett or Hashmi in view of Kris and Beecham. Regarding Kris the applicants state that the reference teaches a kit having a plurality of separated regions and supplying different samples, respectively to these regions. Therefore Kris does not suggest or even hint at supplying the same sample to a plurality of probe regions and obtaining ID information (personal identification) and test information (disease detection)

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at the same time. Therefore applicants submit that Kris while teaching the use of a substrate with multiple regions that do not necessarily have to be 100% identical does not suggest using this type of configuration with a single sample to both identify the subject and perform disease related analysis, i.e., there is no suggestion for using the substrate of Kris in lieu of those in the other references.

This argument has been fully considered but is not persuasive. Applicants are reminded that this is a 103 rejection and Kris is only being relied upon to cure what is missing in the other references. Kris teaches a surface comprising a plurality of spatially discrete regions (Col 1. lines 55-60). As such Kris teaches a DNA microarray that has two separated areas as required by claims. Further it is noted that Hogan, Barrett, and Hashmi all teach hybridizing a solution of genomic DNA to probes that are suitable for personal identification and probes that suitable for checking on a health condition. Thus the combined references (i.e. Hogan and Kris, Barrett and Kris, and Hashmi and Kris) teach hybridizing a DNA microarray with a solution of DNA, wherein the DNA microarray includes a first DNA probe group that reacts with the genes suitable for personal identification and a second DNA probe group that reacts with the disease related genes, wherein the DNA microarray has two separated areas. The fact that Kris alone does not teach supplying the same sample to a plurality of probe regions and obtaining personal identification and test information is irrelevant since the combined references teach all that is required. Further it is noted for the record that KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --

USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (<http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

Nonetheless motivation is present and is provided. In the instant case one of skill in the art would have been motivated to use the array of Kris when practicing the method of Hogan because the array of Kris allows one to analyze the presence or one or more targets (i.e. genes for personal identification and disease related genes) at the same time.

Further the Applicants argue that with respect to claims 32 and 33 neither of the cited references disclose or suggest a testing method in which the hybridization state of each DNA probe obtained from the second DNA probe group is analyzed and test information is generated and written into a memory unit if the first and second identification information match, but a warning is displayed and the writing is inhibited if the identification information does not match. Also, neither reference discloses or suggests reading a second hybridization pattern of the second DNA probe group, analyzing the hybridization state of each DNA probe obtained from the second DNA probe group, generating test information, and outputting test information if the identification information matches, but displaying a warning and inhibiting the reading, analysis, generation, and output if there is no identification match. The applicants state that Beecham merely discloses transmitting records when a biometric data match is found.

This argument has been fully considered but is not persuasive. Beecham teaches a method wherein biometric data submitted by a user is compared to stored

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biometric data (column 18, lines 8-20). In the instant case the biometric data submitted by the user is being interpreted as the identification information from the microarray and the stored biometric data is being interpreted as the identification information on the medical card. Beecham teaches that when the biometric data submitted by the user matches the stored biometric data then the medical data can be obtained (col 8, lines 55-65). Thus Beecham teaches a method comprising comparing the identification information on the microarray to the identification information on the medical card and releasing medical data when there is a match. Beecham also teaches that when the biometric data submitted by the user does not match the stored biometric data then a request for new or revised biometric data is sent and no test information is released until the biometric data match (col 18, lines 14-19). In the instant case the request for new or revised biometric data is being interpreted as a warning. Since the test information is not released if there is no match the step of writing the test results would also be inhibited because there would be nothing to write. Further it would be obvious to also inhibit the second reading step, the generation step, and the output step if the comparison step indicated that the identification information did not match because if the test information is not going to be released then there's no point in reading, generating, and outputting it. For these reasons the rejections are all maintained.

### ***Conclusion***

9. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda M. Shaw whose telephone number is (571) 272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw  
Examiner  
Art Unit 1634

/Carla Myers/  
Primary Examiner, Art Unit 1634